APPLICATION TO REQUEST USE OF LaPRAMS DATA

Authorship includes all written, authored publications (journal articles, manuscripts, abstracts, presentations, reports, newsletters, fact sheets, etc.).

I. Submission of Journal Articles for Publication

The LaPRAMS project will abide by the authorship guidelines listed in Chapter 8 of the 2012 LaPRAMS Protocol (Request from LaPRAMS Project Coordinator). The user/investigator must provide proper credentials to use the data based on past research, employment, and education.

A. For all internal and external Office of Public Health (OPH) applicants*: All internal and external OPH applicants* must fill out an **Application for Use of LaPRAMS Data in Research or Administration of a Program** (Attachment 1) prior to analysis and/or release of PRAMS data for publication. In addition, all submissions expected to result in journal articles or publications (excluding abstracts and presentations) will require a **mini-proposal** (Attachment 1)**.** All applicants must sign a **Confidentiality Agreement** (Attachment 4) prior to publication. All manuscripts must also be reviewed by the LaPRAMS Analysis Working Group prior to publication. This applies to all requests for record level data.

B. For all CDC PRAMS Requesters, other PRAMS states, and external researchers endorsed by the CDC: Louisiana has agreed to give approval on a case-by-case basis to all CDC PRAMS requests for use of the data. Any member of the CDC PRAMS team must submit a mini-proposal prior to publication. All CDC-authored manuscripts will not be submitted for publication or to a conference until the LaPRAMS Analysis Working Group have had the opportunity (at least two weeks) to review and provide comments. The LaPRAMS Analysis Working Group must provide approval prior to publication. External Researchers endorsed by the CDC must sign the **Agreement for Sharing Data with Non-CDC Researchers** with the CDC and must be forwarded with all supporting documents prior to approval. All requests for data from the CDC PRAMS team, other PRAMS states, and external researchers endorsed by the CDC must include a mini-proposal with supporting documents. All PRAMS applicants and external researchers must allow at least 2 weeks for a written response of their application. The LaPRAMS Analysis Working Group must provide approval prior to publication.

II. Review of Abstracts or Presentations

For all submissions for abstracts or presentations, all internal and external OPH applicants* must fill out an **Application for Use of LaPRAMS Data in an Abstract or Presentation** (Attachment 2) and sign a **Confidentiality Agreement** (Attachment 4) prior to use of LaPRAMS data. The applicant is also required to provide a one to two page summary (in lieu of mini-proposal) of the proposed study outlining the background, anticipated scientific benefits of the research, target population, specific research questions, statistical methods to be used to examine the research questions, and forms in which and to whom results of the study will be released prior to analysis and/or

release of LaPRAMS data. One week needs to be provided for review of the abstract or presentation by the LaPRAMS Analysis Working Group. A miniproposal is required if the researcher intends to develop a manuscript from the abstract.
CDC-authored abstracts will not be submitted for presentation until the LaPRAMS Analysis Working Group have had an opportunity to review and provide comments. The LaPRAMS Analysis Working Group must provide approval prior to the presentation. At least one week needs to be provided for review of the abstract for presentation. A mini-proposal is required if the researcher intends to develop a manuscript from the abstract.

III. Requests for Aggregate Data
All requests for aggregate data or use of aggregate data for reports, newsletters, and fact sheets must be accompanied by the **Aggregate Data Requests for Use of Confidential LaPRAMS Data** (Attachment 3).

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* External researchers include all individuals or organizations not employed by the Office of Public Health. These include individuals or agencies under contract with the Office of Public Health and all other offices of Department of Health and Hospitals. External researchers do not include CDC PRAMS. CDC PRAMS members will be held responsible for all confidentiality and application arrangements detailed in the Memorandum of Understanding and the 2003 LaPRAMS Project Protocol.
A state data release policy addressing external researcher requests should describe the following elements: 1) documentation for the proposed research; 2) a signed agreement from the researcher that protects the state against breaches of confidentiality and prevents any potential misuse of the data; 3) how the data will be given to the researcher; 4) how the state will monitor access given to external researchers; and 5) security procedures during the analysis and after the analysis has been completed (Appendix R, 2003 LaPRAMS Protocol)

Exceptions for release of data:
All confidential data shall be made available to the state health officer when necessary for the purpose of controlling nuisances dangerous to the public health, including but not limited to communicable, contagious, and infectious diseases (LSA-R.S.40.3.1B); or to other agencies or medical researchers when the confidential information is necessary to carry out the duties of the agency or researcher in the investigation, control, or surveillance of disease, as determined by the Office of Public Health (LSA-R.S.40.3.1C). Any disclosure to other agencies of researchers shall include only the information necessary for the stated purpose of the request, and shall be made only upon written agreement that the information will be kept confidential and not be further disclosed without written authorization by the LaPRAMS Principal Investigator.

LOUISIANA PREGNANCY RISK ASSESSMENT MONITORING SYSTEM (LaPRAMS)
REVIEW PANEL
DEPARTMENT OF HEALTH AND HOSPITALS, OFFICE OF PUBLIC HEALTH

APPLICATION PROCEDURE FOR USE OF LaPRAMS DATA

The Louisiana Pregnancy Risk Assessment Monitoring System (LaPRAMS) Review Panel and Analysis Working Group is charged with reviewing applications for use of LaPRAMS data to assure that the proposals are of scientific merit, that the applicant and proposed users will maintain the confidentiality of the data and that the confidentiality of the subjects providing the data are protected. Further, where health research is involved, the Panel is charged with assuring that the study design selects subjects on a scientific basis, that the investigators/researchers are deemed qualified based on past research, employment, and education; that where appropriate, the approval of an institutional review board has been obtained; and, that the informed consent process and forms follow the guidelines outlined in Louisiana Administrative Code (LAC) 48:V.11709 and Louisiana Statute (LSA-RS) 40.3.1.

Steps in processing an Application for Use of LaPRAMS Data:

1. The applicant must complete and submit an Application for Use of LaPRAMS Data (Attachment 1) along with supporting documents and a confidentiality statement (Attachment 4) to the LaPRAMS Project Coordinator.

2. The Project Coordinator will review the application for completeness and direct completed applications to members of the LaPRAMS Analysis Working Group.

3. The LaPRAMS Analysis Working Group members will review the application and recommend approval or disapproval based on criteria set forth in LAC 48:V.11709 and LSA-RS.40.3.1.

4. After action by the LaPRAMS Analysis Working Group members, the application will be returned to the Project Coordinator. The Project Coordinator will notify the applicant of approval or disapproval, as appropriate. All applicants must allow at least two weeks for a written response to their application for use of LaPRAMS data in Research or Administration of a Program. All applicants must allow at least one week for a written response to their application for use in an Abstract or Presentation.

5. If an application is disapproved, the LaPRAMS Analysis Working Group will provide the applicant with an explanation for the disapproval. The Project Coordinator will notify the applicant of his/her right to revise the application and reapply, or to request a hearing before the full LaPRAMS Steering Committee.

6. Records of LaPRAMS Analysis Working Group actions relative to the Application for Use of LaPRAMS Data shall be maintained in the manner stated in the Confidentiality Agreement (Attachment 4).

7. Charge for each application is set at $100 per use for all external research applicants.

ATTACHMENT 1

APPLICATION FOR USE OF LaPRAMS DATA IN RESEARCH OR ADMINISTRATION OF A PROGRAM

Date of Application:
Name/Contact Person:
Affiliation:
Address:
Telephone Number:
Fax Number:
E-mail Address:

I. Please provide the following descriptions:

A. Statement of Research/Administrative Use: Attach curriculum vitae of all researchers. All applicants must submit a mini-proposal that contains the following information on the proposed research (label Enclosure 1):

- background, objectives, target population, and methodology of the study
- anticipated scientific or medical benefits of the research
- IRB approval status and informed consent process if applicable
- specific research questions to be addressed
- statistical methods to be used to examine the research questions
- forms in which and to whom results of the study will be released

B. What software will be used to analyze the data? (Note: software must be used that can handle weighted data sets.)

C. Information containing personal or institutional information or aggregated data with cell sizes under five will not normally be supplied by LaPRAMS. If record level data with identifiers is requested, justify why this is needed. What provisions will be made for maintaining confidentiality?

II. Definition of Records Requested:

Type of Records to be used: PRAMS_____ Birth_____*
*Note: If requesting Birth Certificate variables, a separate request must be made for Vital Records data through Darlene Smith's Office (telephone number 504-593-5100).

Strata:
Approximate length of time records/information will be used:
Where the data will be analyzed:

Format Required: Hard-copy_____ Electronic_____
Variables (Electronic Records): Please provide a layout (label Enclosure 2).
Record level data without identifiers (please supply variables on a separate sheet)
Aggregate data (please supply description of the tables to be produced):

III. Means of Protecting Confidential Records:
Locked Cabinet/Vault:_____ Password_____ Other (please specify)_____

Method of Record Destruction at Completion of Study/Administrative Use:

IV. Access to Confidential Records:
Name(s) and Classification(s) of Person(s) to be Authorized Access to Confidential Records*:
Name:
Classification:
Telephone Number:
LaPRAMS Researcher on this project:

V. Statement of Research Assurances:
The applicant states that data obtained from LaPRAMS procured under this agreement will only be published in aggregate, no individual participants will be identified, and that the strictest procedures will be followed to protect the data from unwarranted disclosure and to protect the privacy of study subjects and their families. The applicant understands that hard-copy records are NOT to be duplicated without prior written approval and that electronic records containing identifiers are to be stored on one secure computer. A backup diskette or data tape may be maintained in locked storage. Applicant further agrees that the records will be used only for the stated purpose and that no identifying information will be released to other OPH programs, employees, or non-OPH persons without the specific prior approval of the LaPRAMS Analysis Working Group.

Signature:_____ Name (print or type):_____ Date:_____

Signature:_____ Name (print or type):_____ Date:_____

Signature:_____ Name (print or type):_____ Date:_____

VI. Panel Action:
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____

Comment of Reviewers:
*Note: Attach a confidentiality statement executed by each person who will have access to electronic and/ or hard-copy records.

ATTACHMENT 2

APPLICATION FOR ACCESSING CONFIDENTIAL LaPRAMS DATA FOR USE IN AN ABSTRACT OR PRESENTATION

Date of Application:
Name/Contact Person:
Affiliation:
Address:
Telephone Number:
Fax Number:
E-mail Address:

I. Please provide the following descriptions:

A. Statement of Research/Administrative Use:
For abstracts and presentations, the applicant will submit a one to two page summary (in lieu of mini-proposal) outlining the background, anticipated scientific benefits of the research, target population, specific research questions, statistical methods to be used to examine the research questions, and forms in which and to whom results of the study will be released. A mini-proposal will still be required if the researcher decides at a later date to develop a manuscript from the abstract or presentation.

B. What software will be used to analyze the data? (Note: software must be used that can handle weighted data sets.)

C. Information containing personal or institutional information or aggregated data with cell sizes under five will not normally be supplied by LaPRAMS. If record level data with identifiers is requested, justify why this is needed. What provisions will be made for maintaining confidentiality?

II. Definition of Records Requested:
Type of Records to be used: PRAMS_____ Birth_____*
*Note: If requesting Birth Certificate variables, a separate request must be made for Vital Records data through Darlene Smith's Office (telephone number 504-593-5100).

Strata:
Approximate length of time records/information will be used:
Where the data will be analyzed:

Format Required: Hard-copy_____ Electronic_____
Variables (Electronic Records): Please provide a layout (label Enclosure 2).
Record level data without identifiers (please supply variables on a separate sheet)
Aggregate data (please supply description of the tables to be produced):

III. Means of Protecting Confidential Records:
Locked Cabinet/Vault:_____ Password_____ Other (please specify)_____

Method of Record Destruction at Completion of Study/Administrative Use:

IV. Access to Confidential Records:
Name(s) and Classification(s) of Person(s) to be Authorized Access to Confidential Records* (list requested information for each person authorized)

Name:
Classification:
Telephone Number:

V. Statement of Research Assurances:
The applicant states that data obtained from LaPRAMS procured under this agreement will only be published in aggregate, no individual participants will be identified, and that the strictest procedures will be followed to protect the data from unwarranted disclosure and to protect the privacy of study subjects and their families. The applicant understands that hard-copy records are NOT to be duplicated without prior written approval and that electronic records containing identifiers are to be stored on one secure computer. A backup diskette or data tape may be maintained in locked storage. Applicant further agrees that the records will be used only for the stated purpose and that no identifying information will be released to other OPH programs, employees, or non-OPH persons without the specific prior approval of the LaPRAMS Analysis Working Group.

Signature:_____ Name (print or type):_____ Date:_____

Signature:_____ Name (print or type):_____ Date:_____

Signature:_____ Name (print or type):_____ Date:_____

VI. Panel Action:
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____
Signature:_____ Action (Approve=A/Disapprove=D):_____ Date:_____

LaPRAMS Researcher on this project:_____

Comment of Reviewers:
*Note: Attach a confidentiality statement executed by each person who will have access to electronic and/ or hard-copy records.

ATTACHMENT 3

APPLICATION FOR AGGREGATE DATA REQUEST FOR USE OF CONFIDENTIAL LAPRAMS DATA

Date of Application:
Name/Contact Person:
Affiliation:
Address:
Telephone Number:
Fax Number:
E-mail Address:

I. Please provide the following descriptions:

Variables requested to be used in distributions and tables:

Study Summary* (description of health or medical problem addressed or administrative purpose served by use of data.):

Signature:_____ Name (print or type):_____ Date:_____
Signature:_____ Name (print or type):_____ Date:_____
Signature:_____ Name (print or type):_____ Date:_____
Signature:_____ Name (print or type):_____ Date:_____

Approved by:
_____ Date:_____
_____ Date:_____
_____ Date:_____
_____ Date:_____

Please send/ fax/ or e-mail copies to:
Pregnancy Risk Assessment Monitoring System
DHH-Office of Public Health
PO Box 60630
New Orleans LA 70160
fax: 504-568-3503
e-mail: Adrienne Finley, MPH adrienne.finley@la.gov
*Note: data may not be published or released without separate written authorization by the LaPRAMS Analysis Working Group.

ATTACHMENT 4

LOUISIANA PRAMS CONFIDENTIALITY AGREEMENT

Louisiana Department of Health and Hospitals, Office of Public Health
Pregnancy Risk Assessment Monitoring System, Epidemiology, Assessment, and Evaluation Unit
P.O. BOX 60630
New Orleans, Louisiana 70160
(504) 568-3504

Agreement For Accessing Confidential LaPRAMS Survey Data

All LaPRAMS records are considered confidential in accordance with Louisiana Legislative Statutes (LSAR.S.40.3.1). Confidential records shall be used only for statistical, scientific, and medical research purposes relating to the cause or condition of health. The Louisiana Pregnancy Risk Assessment Monitoring System will release confidential information from these records for research or administrative purposes providing the following conditions are met. Use of and access to any Birth Certificate Information must adhere to Louisiana Administrative Code (LAC 48:V.11709) for the use of vital records in research.

The researcher agrees to the following conditions for accessing confidential LaPRAMS information:

- Data will be used only as proposed. User will not make any copies of the data, and will not release, share or further distribute any data containing complete or partial individual records to anyone who has not cosigned the LaPRAMS Confidentiality Agreement. Data includes all indices and ratios derived from the data. Any person who intentionally discloses the content of LaPRAMS confidential data to a third party, except those who have co-signed the Confidentiality Agreement, shall be subject to a civil penalty in an amount not less than one thousand dollars and not more than five thousand dollars plus court costs, paid by the person whose record was unlawfully disclosed (LSA-R.S. 40-.3.1).
- User will not divulge the identity of any individual or entities distinguished by the data. User will not contact any individuals or entities identified by the data. All follow- up studies involving contact with individuals or next-of-kin identified in certificates or confidential information are prohibited.
- User must acknowledge the data source in all published and unpublished written works and presentations resulting from the data.
- A copy of the final results and any written work must be provided to the LaPRAMS Principle Investigator and Coordinator before publication.
- After work with the data is completed, all copies of the data will be returned to the LaPRAMS Principle Investigator or destroyed.
- The user agrees to indemnify, defend, and hold harmless The Office of Public Health (from damages, litigation, liability, and any expenses including legal fees) in the event of claims or losses.
- After one year, user forfeits claim to data and analyses if they have not submitted a manuscript for publication.

- In the case where analyses result in cell sizes of less than five in either numerator or denominator, all numbers and rates will be replaced with a symbol (i.e., ***) in publications. Identifiable characteristics of individuals that result from analyses will not be used in any publications.
- All confidential information obtained from Vital Records and the LaPRAMS survey will not be used to deny current and/or future benefits or eligibility for services or care.
- Any release of the data derived from Vital Records and PRAMS survey is to contain the following statement: *"This data was supplied in part by the Louisiana Pregnancy Risk Assessment Monitoring System of the Louisiana Department of Health and Hospitals, Office of Public Health, which disclaims responsibility for any analyses, interpretations, or conclusions."*
- One Louisiana PRAMS team member must be included as an author on any publication using data from the LaPRAMS Project.
- Violation of these conditions will automatically result in the voiding of this agreement and may result in the refusal of future research requests. For Vital Records data, violations of these conditions may result in legal action provided under the provision of Louisiana Statues (LSA-R.S. 40:61B).
- All data must be stored in a secure location; and means of protecting confidential records must be provided.
- All researchers must also submit an Application for Use of LaPRAMS Data in Research or Administration of a Program when requesting record level data with or without identifiers (names, addresses, social security numbers, and birth certificate numbers). For abstracts and presentations, all researchers must submit an Application for Accessing Confidential LaPRAMS Survey Data for Use in an Abstract for Presentation.

LOUISIANA PREGNANCY RISK ASSESSMENT MONITORING SYSTEM (LaPRAMS)
ANALYSIS WORKING GROUP
DEPARTMENT OF HEALTH AND HOSPITALS, OFFICE OF PUBLIC HEALTH

Research and Administrative Use of Confidential LaPRAMS Data
Confidentiality Assurance Statement

I, _____, certify that I have read the Louisiana PRAMS Confidentiality Agreement (pages 1-2) and state that identifying information obtained from LaPRAMS data accesses under this assurance of confidentiality will be held in strictest confidence and will be protected against unwarranted disclosure. No data will be published or disclosed from which an individual participant can be identified except upon written authorization of the LaPRAMS Analysis Working Group. I understand that unauthorized disclosure may result in disciplinary action in accordance with departmental policies, Louisiana Statute (LSA-RS) 40:3;1 and Louisiana Administrative Code (LAC) 48:V.11709 as applicable.

Signature_____

Name (typed or printed)_____

Title_____

Date_____

Telephone Number_____